Docket No.: DiSalvo
RCE of Appl. No. 10/726,100

REMARKS

This Amendment is submitted preliminary to the issuance of an Office Action in the present application and in response to the Official Action of January 25, 2006.

Reconsideration of the prior rejections is hereby respectfully requested.

Claims 20-47 are pending in the application> claims 26-29 are withdrawn from consideration and were cancelled. Claims 31-32 are cancelled. New claims 48 and 49 were added. A total of 24 claims is now on file.

The Examiner has rejected claims 20-25 and 30-47 under 35 U.S.C. §112, first paragraph as lacking support for the germanium ranges claimed in claim 20.

Claims 20, 23-25, 30-34, 36-40, 43-45, 47 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,375,219 (hereinafter: "Schmid).

Claim 21 stands rejected under 35 U.S.C. §103(a) over Schmid in view of over U.S. Patent No. 3,752,151 (hereinafter: "Robichaud")

Claim 22 stands rejected under 35 U.S.C. §103(a) over Schmid in view of over U.S. Patent No. 3,816,293 (hereinafter: "Ueda")

Claims 35 and 41-42 stand rejected under 35 U.S.C. §103(a) over Schmid in view of over U.S. Patent No. 4,668,840 (hereinafter: "Kiyama")

Claim 46 stands rejected under 35 U.S.C. §103(a) over Schmid in view of over U.S. Patent No. 5,822,177 (hereinafter: "Popp")

Reference is made to a telephone dicussion with the Examiner on May 24, 2006 in which the disclosed ranges of germanium were discussed.

The interview with the Examiner did not result in agreement regarding the claims. However, applicant submits the current amendment to claim 20 is supported by the disclosure as the following discussion shows.

Docket No.: DiSalvo
RCE of Appl. No. 10/726,100

REJECTION UNDER 35 U.S.C. §112, FIRST PARAGAPH

Applicant has amended claim 20 to set forth the percentage range of 0.01% to 1.85% of germanium and %%-15% fro the dopant. The percentages are fully supported by the disclosure. The lower %age of 0.01% of germanium is supported by the disclosure in paragraph **[0053]** as amended by the orignial disclosure (claim 1) of where the range of 0.01 to 20% was disclosed. Paragraph [0053] also sets forth the range of the dopant.

Furthermore, the Examiner is directed to page 21 of applicant's specification, where sample 4 shows that germanium in the amount of 1.85% was used for an electrode in the medical example as described. Other percentages are also shown in the samples.

Accordingly, applicant's claiming a range of between 0.01 to 1.85% germanium in claim 20 and 30 and 1.1% to 1.85% in claim 48 and 49 is fully supported by the disclosure. The lower 1.1% is likewise disclosed in paragraph **[0053]** as a smaller range.

As far as the Examiner question regarding criticality, it is evident from the samples described in the specification that those percentages are the best mode percentages and in that way "critical".

Since the amended claims are fully supported by the disclosure and the best mode claimed, applicant contends that the rejection under **35** U.S.C. §112, first paragraph has been overcome.

Withdrawal of the rejection of claims 20-25 and 30-47 under 35 U.S.C. §112, first paragraph is thus respectfully requested.

REJECTION UNDER 35 U.S.C. §103(A)

The Examiner's rejection of claim 20, 23-25, 30-34, 36-40, 43-45, and 47 based on the Schmid reference is again respectfully traversed.

Applicant has amended claim 20 and 30 and added new claims 48 and 49 in which the critical percentages of germanium have been set forth. Also, the

%ages of the dopant has been amended to a range between 5%-15% which is fully supported by the disclosure.

At the outset, it is noted that case law shows an applicant is entitled to narrow claimed ranges (temp. pH, %ages) in order to circumvent prior art. See *Warner Jenkinson v. Hilton Davis Chemical Co.* 41 USPQ 1865 (S. Court 1997). Applicant claims a %age range of germanium which is not only outside of the range of the cited reference Schmid, but the samples in the description support them.

The Examiner postulates that parameters and dimensions would be obvious based on Schmid. Clearly, parameters and dimensions of instrumentation must be commensurate with their function. Schmid discloses an electrode for exterior use on a body in EKG measurement. No uses other than a use for EKG are disclosed nor even mentioned in Schmid.

Furthermore, the Examiner states that *Schmid discloses a silver germanium alloy electrode and that silicon is also mentioned.* However, Schmid does not disclose an electrode containing about 0.9% to 1.85% by weight of germanium; between 5% to 25% by weight relative to the germanium of at least one of a non-hydrogenic and shallow hydrogenic acceptor dopant; up to 20% by weight of one or more of the compounds selected from the group consisting of platinum, gold, palladium, iridium, ruthenium, osmium, rhodium, niobium, tantalum, tungsten, aluminum, silicon, zirconium, rare earth elements including hafnium, yttrium and lanthanum; and as a remainder up to 100% by total weight constituted by silver, and wherein the instrument is coated partially or completely with one or more of a material selected from the group consisting of biocompatible, insulating, semi-insulating compounds and ceramic materials.

In other words, the claimed surgical instrument claimed in claim 20 also contains a dopant and contains additions of any one of the enumerated elements. Moreover, the surgical instrument is coated with a material as set forth above.

The Examiner cites the top of col. 7 in Schmid where examples are given. It is significant that only one of the examples in Schmid is directed to a germanium/silver electrode. That electrode does not point in any way to a surgical instrument as claimed in claim 20 or a surgical electrode in claim 30 because

Schmid does not disclose nor teaches a germanium/silver electrode that contains silicon. While the Examiner notes that silicon is *mentioned*, applicant submits that Schmid does not disclose nor teach a germanium/silver electrode which includes silicon. Mere mention of silicon not in the context of germanium/ silver electrode context does not support an obviousness rejection.

A reference used as a basis for an obviousness rejection must contain some motivation for those skilled in the art to direct them for example to uses other than claimed, since there is no motivation to modify a prior art device where the modification would render the device inoperable for its intended purpose; see *McGinley vs. Franklin Sports, Inc.* 60 USPQ2d 1001 (Fed. Cir. 2001). A person skilled in the art of surgical instruments would not look to the art of EKG electrodes, but would look to the art of surgical instruments. It is common knowledge and should be accepted as judicial notice that there is a critical difference in an electrode for use in contacting skin tissue only (i.e. exterior) as compared to a surgical electrode where the instrument comes in contact directly with the biological tissue of a patient (i.e. intrabody use). It is common knowledge that resistance in biological tissue can vary greatly from skin to other tissues and skin has a natural resistance which can be measured.

Regarding claim 23, the Examiner noted that the Schmid electrode *is capable of implantation*, but he has brought forth no evidence, neither intrinsic nor extrinsic in Schmid which would allow or point to such extrapolation.

The Examiner contends that the Schmid reference is capable of emitting infrared radiation. Again there is no support for this assertion and the Examiner gives no evidence from which such a statement can be gleaned. The Examiner does not point to the text in Schmid where such a statement can be gleaned from.

Regarding claim 31 and 32, these claims have been cancelled, which renders their rejection moot.

The Examiner applies a standard amounting to "obvious to try" which is not the proper standard for determining obviousness. In speculating that varying all parameters to try each of numerous choices give no indication of which is critical. The prior art must suggest some desirability of a modification or combination. This not found here. The mere fact that references may be modified

or combined does not make the modification or combination obvious unless the prior art suggested the desirability of the modification or combination, *In re Fritch* 23 USPQ2d 1780 (Fed. Cir. 1992).

The further rejections are typical of the "smorgasbord" approach in which for each element in the claim a different reference is cited for that element, without regard of whether the teachings of the references can be combined The

Schmid electrode give at most a general guidance as to a particular form of topical electrode for EKG measurement. Just adding further elements do not reach the level of obviousness for the claimed surgical tool.

With respect to claim 21, the Examiner cites Robichaud, a disposable electrode for EKG measurement cited for lamination. Robichaud cannot be combined with Schmid since Robichaud is directed only to a disposable electrode. Schmid does not *neglect* to disclose laminate as proposed by the Examiner; Schmid did not need nor want to include laminate because of its unique construction. There is nothing found in Schmid that would point to the desire to laminate. The disposable electrode foresees to be used with electric paste, the Schmid electrode is an electrode for use without paste. There is no sense or purpose to combine the two.

With respect to Ueda, the Examiner cites the combination of Schmid with Ueda to disclose fusion. Again the Examiner uses *neglect* as a term. Ueda is however directed to an electrode for seawater electrolysis. Lead which is the predominant compound in such an electrode, which is not used in either the Schmid electrode nor in the claimed surgical instrument as in claim 20 or the electrode claimed in claim 30. Applicant contends there is nothing "neglected" here because Schmid does not in the least need the fusion effect for the purpose it is used. The wild mixture of electrodes the Examiner assembled have all the name electrode but have really such divergent uses as to have nothing to do with each other.

The Examiner finds that Schmid *neglects* to disclose microcrystals and cited Kiyama. Microcrystal structure is important where the surgical instrument is used in biological tissue other than skin. Again the combination between Schmid

and Kiyama has not been shown to be supported by any motivation to do so. Since Schmid does not even mention microcrystals.

With respect to claim 46, the Examiner cites again the Popp reference to show Schmid neglected to disclose fractal surfaces. Fractal surface are however no part of the Schmid electrode and Schmid has no use for a fractal surface since that electrode benefits only from as much contact or a smooth surface as possible. Again, there is complete lack of motivation to combine the two references; in fact the opposite is desired. Since Schmid and Popp cannot be combined, they are not applicable to the claimed surgical instrument or the claimed electrode.

CONCLUSION

Applicant remains with the position that the Examiner has not made out prima facie that either of the references cited can indeed be technically combined with the Schmid reference, much less to be showing that the claimed surgical instrument and electrode are obvious. Based thereon, the rejection of the claims as being obvious under the respective combination should be withdrawn.

In further examining this application, the Examiner should take the foregoing into account.

Respectfully submitted,

By: _____
Ursula B. Day
Attorney for Applicant
Reg. No. 47,296

Date: May 25, 2006
350 Fifth Avenue
Suite 4714
New York, N.Y. 10118
(212) 244-5500
UBD:af